

In the Claims

The following amendments are made with respect to the claims in the International application PCT/GB2004/005331. Please note that these amendments are also made with respect to the Annexes attached to the International Preliminary Examination Report (IPER) wherein claims 22-24 were added in the international application.

This listing of claims will replace all prior versions and listings of claims in this application.

1-24 (cancel).

25 (new). A (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values (Å) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-Mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values (Å) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values (Å) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw),

2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw);

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1030.2 (w) and 85.4 (vs);

e) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
2877 (m), 1601 (s), 1585 (s), 1363 (vs), 1028.2 (w), 320 (m) and 118 (vs);

f) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as an acetone solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ) of:  
1602 (s), 1585 (s), 1363 (vs), 322 (m) and 118 (vs);

g) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a tetrahydrofuran solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1601 (s), 1585 (s), 1363 (vs), 323 (m) and 119 (vs);

h) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a methyl ethyl ketone solvate, exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1600 (s), 1585 (s), 1363 (vs), 319 (m) and 118 (vs); and

i) (+)- or (-)-*erythro*-mefloquine hydrochloride, which is substantially in the form of thick columns, cuboids, cubes or cube-like particles.

26 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25, in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of: 5.95 (s) and 4.02 (w).

27 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claim 26, wherein the pattern also has peaks, expressed in d-values ( $\text{\AA}$ ), of:

11.2 (vs), 9.0 (s), 7.4 (w), 6.8 (w), 6.3 (s), 6.1 (m), 6.0 (m), 5.95 (s), 5.58 (m), 5.42 (m), 4.91 (m), 4.87 (w), 4.47 (s), 4.55 (w), 4.16 (vs), 4.12 (s), 4.10 (s), 4.02 (w), 3.82 (vs), 3.77 (w), 3.74 (s), 3.71 (vs), 3.64 (m), 3.47 (w), 3.40 (w), 3.33 (w), 3.31 (m), 3.27 (w), 3.25 (w), 3.11 (m), 3.04 (m), 2.94 (m), 2.92 (w), 2.75 (w), 2.70 (m), 2.68 (w), 2.64 (m), 2.62 (m), 2.54 (w),

2.45 (w), 2.39 (w), 2.35 (w), 2.30 (w), 2.29 (w), 2.25 (w), 2.22 (w), 2.18 (w), 2.17 (w), 2.08 (w), 1.99 (m), 1.95 (w), 1.91 (w), and 1.88 (w).

28 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25, comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw).

29 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25, comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw).

30 (currently amended). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claim 25, which exhibits a characteristic X-ray powder diffraction pattern as exhibited in any of Figures 1, 2 and 3.

31 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25, in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1030.2 (w) and 85.4 (vs).

32 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claim 25, in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

2877 (m), 1601 (s), 1585 (s), 1363 (vs), 1028.2 (w), 320 (m) and 118 (vs).

33 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25 which, as an acetone solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ) of:

1602 (s), 1585 (s), 1363 (vs), 322 (m) and 118 (vs).

34 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride, according to claim 25 which, as a tetrahydrofuran solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1601 (s), 1585 (s), 1363 (vs), 323 (m) and 119 (vs).

35 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claim 25, which, as a methyl ethyl ketone solvate, exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1600 (s), 1585 (s), 1363 (vs), 319 (m) and 118 (vs).

36 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claims 25, which is substantially in the form of thick columns, cuboids, cubes or cube-like particles.

37 (new). The (+)- or (-)-*erythro*-mefloquine hydrochloride according to claim 36, in crystalline form B or C.

38 (new). A process for the preparation of a (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47, (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw); and

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1030.2 (w) and 85.4 (vs);

wherein said process comprises either:

i) dissolution of another solid form of (+)- or (-)-*erythro*-mefloquine hydrochloride at a temperature from 20°C to 100°C in a solvent, to form a concentrated solution, optionally seeding and cooling the solution to precipitate (+)- or (-)-*erythro*-mefloquine hydrochloride, stirring the suspension for a time sufficient to complete formation of the desired crystalline form, removing the solvent, and drying the solid residue, or

ii) dissolution of another solid form of (+)- or (-)-*erythro*-mefloquine hydrochloride at a temperature from 20°C to 100°C in a solvent, to form a concentrated solution, optionally seeding and adding a sufficient amount of a non-solvent to precipitate (+)- or (-)-*erythro*-mefloquine hydrochloride, stirring the suspension for a time sufficient to complete formation of the desired crystalline form, removing the solvent, and drying the solid residue.

39 (new). A process for the preparation of a crystalline form of (+)- or (-)-*erythro*-mefloquine hydrochloride, comprising the steps of:

- a) dissolving or suspending substantially water-free (+)- or (-)-*erythro*-mefloquine free base at a temperature from 10 to 80°C in ethanol,
- b) adding aqueous HCl and water at a concentration, such that the formed (+)- or (-)-*erythro*-mefloquine hydrochloride is insoluble,
- c) shaking or stirring the resultant suspension and optionally also cooling it, and
- d) isolating the precipitate and drying the solid residue.

40 (new). The process, according to claim 39, comprising the steps of:

- a) dissolving or suspending substantially water-free (+)- or (-)-*erythro*-mefloquine free base at a temperature from 40 to 80°C in ethanol,
- b) maintaining the temperature and adding aqueous HCl to form (+)- or (-)-*erythro*-mefloquine hydrochloride under shaking or stirring,
- c) slowly decreasing the temperature continuously or continuously and stepwise down to about 10°C to 30°C,
- d) adding water at the decreased temperature to reduce solubility of (+)- or (-)-*erythro*-mefloquine hydrochloride,
- e) shaking/stirring at the decreased temperature, and
- f) isolating the precipitate and drying the solid residue.

41 (new). The process according to claim 39, for the preparation of

a (+)- or (-)-*erythro*-mefloquine hydrochloride in the form of cubes or cube-like forms, having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values (Å) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values (Å) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81

(vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47, (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw); and

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1030.2 (w) and 85.4 (vs);

wherein said process comprises the steps of:

- a) dissolving or suspending substantially water-free (+)- or (-)-*erythro*-mefloquine free base at a temperature from 65 to 80°C in absolute ethanol,
- b) maintaining the temperature and continuously adding within 5 to 20 minutes under shaking or stirring concentrated aqueous HCl such that the water content in the ethanol/water mixture is from 20 to 3 and preferably 15 to 5 volume percent, to form a solution of (+)- or (-)-*erythro*-mefloquine hydrochloride in ethanol/water,
- c) continuously decreasing the temperature at a rate of 0.2 to 1K/min down to about 20°C to 30°C, or continuously decreasing the temperature in a first step at a rate of 0.2 to 1K/min 5 to 20°C lower as in step a), adding 0.5 to 2.5 percent by weight, referred to the amount of (+)- or (-)-*erythro*-mefloquine hydrochloride, of crystal seeds of the mefloquine hydrochloride according to any of claims 1 to 6, in cubic or cube-like morphological form, stirring 15 to 30 minutes, and then continuously decreasing the temperature at a rate of 0.1 to 1K/min down to about 20°C to 30°C,
- d) adding water at the decreased temperature over 30 to 60 minutes in such amount that the water content in the ethanol/water mixture is from 65 to 85 volume percent,

- e) continuing shaking/stirring for 1 to 2 hours at the decreased temperature, and
- f) isolating the precipitate and drying the solid residue.

42 (new). The process according to claim 39, which comprises storing the mixture between steps (d) and (e).

43 (new). A process for the manufacture of (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

2877 (m), 1601 (s), 1585 (s), 1363 (vs), 1028.2 (w), 320 (m) and 118 (vs),

wherein said process comprises the steps of:

- a) treating with or without vacuum a methyl ethyl ketone solvate of (+)- or (-)-*erythro*-mefloquine hydrochloride at a temperature from 20°C to 100°C, preferably 30°C to 70°C, to remove the methyl ethyl ketone, or
- b) suspending a methyl ethyl ketone solvate of (+)- or (-)-*erythro*-mefloquine hydrochloride in a non-solvent, stirring for a time sufficient to remove methyl ethyl ketone from the solvate, and isolating and then drying the crystals.

44 (new). A process for the manufacture of (+)- or (-)-*erythro*-mefloquine hydrochloride comprising the steps of:

- a) dissolving (+)- or (-)-*erythro*-mefloquine hydrochloride in acetone, tetrahydrofuran or methyl ethyl ketone at a temperature from 40 to 80°C to form a concentrated, saturated or super-saturated solution, cooling and stirring the cooled suspension for a time period sufficient to form the solvate, and isolating and drying the crystals, or
  - b) suspending (+)- or (-)-*erythro*-mefloquine hydrochloride in acetone or tetrahydrofuran, stirring the suspension at a temperature from 20 to 35°C for a time sufficient to form the solvate, and isolating and drying the crystals,
- and wherein the (+)- or (-)-*erythro*-mefloquine hydrochloride has one or more of the following characteristics:

i) as an acetone solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ) of:

1602 (s), 1585 (s), 1363 (vs), 322 (m) and 118 (vs);



ii) as a tetrahydrofuran solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1601 (s), 1585 (s), 1363 (vs), 323 (m) and 119 (vs); and

iii) as a methyl ethyl ketone solvate, exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1600 (s), 1585 (s), 1363 (vs), 319 (m) and 118 (vs).

45 (new). A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-Mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw);

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1030.2 (w) and 85.4 (vs);

e) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

2877 (m), 1601 (s), 1585 (s), 1363 (vs), 1028.2 (w), 320 (m) and 118 (vs);

f) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as an acetone solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ) of:

1602 (s), 1585 (s), 1363 (vs), 322 (m) and 118 (vs);

g) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a tetrahydrofuran solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1601 (s), 1585 (s), 1363 (vs), 323 (m) and 119 (vs);

h) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a methyl ethyl ketone solvate, exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:

1600 (s), 1585 (s), 1363 (vs), 319 (m) and 118 (vs); and

i) (+)- or (-)-*erythro*-mefloquine hydrochloride, which is substantially in the form of thick columns, cuboids, cubes or cube-like particles.

46 (new). The pharmaceutical composition, according to claim 45, comprising a (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47, (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27

(vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw); and

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1030.2 (w) and 85.4 (vs).

47 (new). A method for the treatment of malaria, a movement or neurodegenerative disorder, or an inflammatory or autoimmune disease wherein said method comprises administering, to a patient in need of such treatment, a (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-Mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47, (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values ( $\text{\AA}$ ) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw);

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1030.2 (w) and 85.4 (vs);

e) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
2877 (m), 1601 (s), 1585 (s), 1363 (vs), 1028.2 (w), 320 (m) and 118 (vs);

f) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as an acetone solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ) of:  
1602 (s), 1585 (s), 1363 (vs), 322 (m) and 118 (vs);

g) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a tetrahydrofuran solvate, is in the form of a crystalline pseudo-polymorph which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1601 (s), 1585 (s), 1363 (vs), 323 (m) and 119 (vs);

h) (+)- or (-)-*erythro*-mefloquine hydrochloride which, as a methyl ethyl ketone solvate, exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of:  
1600 (s), 1585 (s), 1363 (vs), 319 (m) and 118 (vs); and

i) (+)- or (-)-*erythro*-mefloquine hydrochloride, which is substantially in the form of thick columns, cuboids, cubes or cube-like particles.

48 (new). The method, according to claim 47, which comprises administering a (+)- or (-)-*erythro*-mefloquine hydrochloride having one or more of the following characteristics:

a) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values (Å) of: 5.95 (s) and 4.02 (w);

b) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 30 to 150  $\mu\text{m}$ , in a crystalline form which exhibits a X-ray powder diffraction pattern with peaks expressed in d-values (Å) of:

22.3 (vw), 11.2 (vs), 9.0 (w), 8.2 (vw), 7.4 (vw), 6.8 (vw), 6.5 (vw), 6.3 (vw), 6.1 (vw), 6.0 (vw), 5.94 (vw), 5.61 (m), 5.42 (w), 4.89 (vw), 4.74 (w), 4.54 (w), 4.12 (s), 4.02 (w), 3.81 (vvs), 3.74 (vs), 3.70 (vw), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.34 (vw), 3.31 (vw), 3.26 (vs), 3.11 (vw), 3.04 (w), 2.97 (vw), 2.94 (vw), 2.81 (vw), 2.75 (m), 2.71 (w), 2.69 (w), 2.64 (w), 2.62 (w), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.27 (vw), 2.24 (vw), 2.22 (vw), 2.17 (vs), 2.08 (vw), 2.06 (vw), 2.04 (vw), 1.94 (w), 1.91 (vw) and 1.88 (vw);

c) (+)- or (-)-*erythro*-mefloquine hydrochloride comprising particles having a size distribution of 1 to 10  $\mu\text{m}$ , in a crystalline form which exhibits a characteristic X-ray powder diffraction pattern with peaks expressed in d-values (Å) of:

11.2 (m), 9.0 (w), 8.30 (vw), 7.4 (vw), 6.8 (vw), 6.3 (w), 6.1 (vw), 6.0 (vw), 5.95 (vw), 5.59 (w), 5.42 (w), 4.91 (vw), 4.74 (w), 4.55 (vw), 4.16 (w), 4.12 (s), 4.03 (w), 3.82 (vvs), 3.75 (w), 3.71 (w), 3.64 (w), 3.55 (w), 3.47 (vw), 3.40 (vw), 3.33 (w), 3.26 (w), 3.11 (vw), 3.04 (vw), 2.94 (vw), 2.75 (w), 2.71 (vw), 2.69 (vw), 2.64 (w), 2.62 (vw), 2.54 (vw), 2.46 (vw), 2.43 (vw), 2.40 (vw), 2.35 (vw), 2.30 (vw), 2.26 (vw), 2.22 (vw), 2.17 (w), 2.08 (vw), 2.06 (vw), 1.99 (vw), 1.91 (vw) and 1.89 (vw); and

d) (+)- or (-)-*erythro*-mefloquine hydrochloride in a crystalline form which exhibits characteristic Raman bands, expressed in wave numbers ( $\text{cm}^{-1}$ ), of: 1030.2 (w) and 85.4 (vs).